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09/855,143	05/14/2001	Karl F. Gruber	41821.1000	1123

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EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Restart

DETAILED ACTION

Status of the Claims

The amendment filed May 25, 2003 is acknowledged and has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by Bieber et al (Mass Spectrometric Immunoassay, Analytical Chemistry 1995, 67, 1153-1158).

Bieber et al disclose a method to determine an analyte by capturing and isolating an antigen. Bieber et al disclose providing a filter pipette tip (MSIA-tip) for retaining an affinity reagent-antigen complex (Figure 1 and description of Figure 1). Bieber et al disclose incubating antibodies covalently immobilized to a solid support with an antigen-containing sample. Bieber et al disclose MSIA reagent comprised of beads having protein A (affinity ligand) on their surface and affinity purified rabbit antibodies as MSI A reagents. Bieber et al disclose that after incubation and the formation of antibody/antigen complexes, the complexes are washed and then the antigen is eluted onto a mass spectrometer probe tip using a solution of MALDI matrix. Bieber et al. further disclose that after the antigen is eluted that Time-of-flight mass spectrometry is performed (page 1153 col 2, see also Experimental Section). Bieber et al also disclose that a single assay can be used to screen biological systems for the presence of

multiple, mass-resolved antigens. Bieber et al also disclose that antigen signals are observed to determine the presence and amount of an antigen or its antigen variant (p. 1158).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bieber et al (Mass Spectrometric Immunoassay, Analytical Chemistry 1995, 67, 1153-1158) in view of Ogura et al (UK Patent 2,030,294).

See above for teachings of Bieber et al.

Bieber et al differ from the instant invention in failing to teach the use of anti-human β2-microglobulin antibody as an affinity reagent.

Ogura et al disclose anti-human β2-microglobulin coated on the surface of a solid support. Ogura et al disclose this anti-human β2-microglobulin allows for a composition for use in the qualitative or quantitative determination of human β2-microglobulin, which has superior storage stability and which can rapidly give reliable results with good repoductibility and a high degree of accuracy without being hampered by other proteins that may be contained in an assay sample (p. 1 and abstract).

It would have been obvious to one of ordinary skill in the art to substitute the anti-human β2-microglobulin antibody as taught by Ogura et al for the affinity purified rabbit

antibodies of Bieber et al because Ogura et al shows that this anti- human β2-microglobulin antibody allows for a composition for use in the qualitative or quantitative determination of human β2-microglobulin, which has superior storage stability and which can rapidly give reliable results with good reproducibility and a high degree of accuracy without being hampered by other proteins that may be contained in an assay sample.

Response to Arguments

Applicants arguments filed May 25, 2003 have been fully considered but are not found persuasive.

Applicant argues that the Bieber journal article cited by the Examiner does not constitute a description of the invention in a printed publication before the invention was made by Applicants in that at least one of the Applicants is an author of the journal article and conceived the broadest claim of the invention before the publication of the journal article. This is not found persuasive because Applicant has not submitted a declaration that demonstrates Allan L. Bieber, Jennifer R. Krone and Peter Williams did not take part in the conception of the subject matter disclosed and claimed in the instant patent application, nor did Applicant disclose the work performed by Allan L. Bieber, Jennifer R. Krone and Peter Williams in connection with the instant reference. Therefore, the 102 (a) rejection stands because the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. Further, even if Allan L. Bieber, Jennifer R. Krone and Peter Williams are removed from the reference, the reference is still by another because Karl Gruber, and Kemmons Tubbs are listed as co-inventors in the current application and are not listed as authors of the Bieber et al reference and the inventors of the current application do not match up with the authors of the Bieber reference. Therefore, it would still be by others.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
June 6, 2003

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641

6/11/03